

(21%) patients. Peri-procedural bradycardia occurred in 99 (24.5%) patients but only 61 (15%) required atropine. Patients with HI had a significantly increased risk of stroke (OR=2.6, 95% CI 1.2-5.9), myocardial infarction (MI) (OR=4.5, 95% CI 1.2-16.9) or death (OR=2.7, 95% CI 1.0-7.6) in the peri-operative period. The odds ratio for the combined endpoint of stroke, MI or death was 3.6 (95% CI 1.8-6.9) in patients with HI.

Conclusions: HI is common after CAS and often requires pharmacological intervention. Patients with HI are at an increased risk for stroke, MI or death and require close monitoring.

Noon

1116-5 Elevated Preprocedural C-Reactive Protein Levels Predict Death and Stroke in Patients After Carotid Artery Stenting

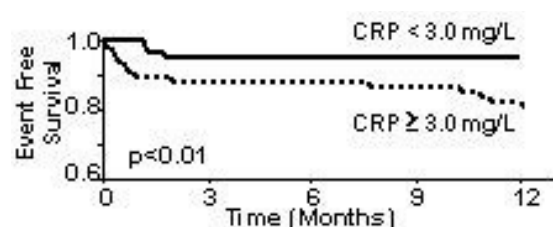
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Background: Elevated pre-procedural C-reactive protein (CRP) levels are associated with the composite endpoint of death or myocardial infarction in patients undergoing percutaneous coronary intervention. We sought to determine whether elevated pre-procedural CRP levels predict the composite endpoint of death or stroke in patients who undergo carotid artery stenting.

Methods: Between December 1999 and August 2002, we examined 133 patients with pre-procedural CRP levels who underwent carotid artery intervention from a carotid interventional registry. Using a CRP level of 3.0 mg/L as the cutoff, patients were sub-divided into high CRP (n=67) and low CRP (n=66) groups. The 30 day and 12 month composite endpoint of death or stroke were compared between the groups.

Results: No significant differences in baseline demographics were found between the two groups (including age, gender, coronary artery disease, or prior stroke or transient ischemic attack), except for hyperlipidemia which was significantly higher in the low CRP group. For the entire cohort, the death/stroke rates at 30 days and 12 months were 5% (7 events) and 12% (16 events) respectively. The 30 day death/stroke rate was significantly higher in the high CRP group vs. the low CRP group (10% vs. 0%, p<0.01). This increased event rate was sustained at one year (19% vs. 5%, p<0.01).

Conclusion: In patients who undergo carotid artery stenting, pre-procedural CRP levels predict the composite endpoint of death or stroke at 30 days and 12 months.



Noon

1116-6 Long-Term Clopidogrel Therapy Following Percutaneous Coronary Intervention Improves Clinical Outcome but Is Not Associated With Increased Bleeding: New Insights From the CREDO Trial

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Background: In the CREDO trial, the 1-year incidence of major adverse clinical events (MACE) among patients undergoing or likely to undergo coronary stenting was significantly reduced by a pre-procedure clopidogrel loading dose plus 1 year of clopidogrel compared with no loading dose and 28 days of clopidogrel. Because most patients undergoing coronary stenting receive 4 weeks of dual antiplatelet therapy with aspirin and clopidogrel, we sought to determine predictors of bleeding and occurrence of major events between day 29 and 1 year among patients enrolled in the CREDO trial.

Methods: Patients who survived to day 29 were included (n=2068) in this intent-to-treat analysis. Minor and major bleeding events (TIMI criteria) were pooled into a composite of any bleeding. MACE was a composite of death, non-fatal myocardial infarction (MI) and stroke.

Results: From day 29 through 1 year there were 138 bleeding events, 68 in the clopidogrel and 70 in the placebo arm (p=0.84). Of these, 112 (81%) were procedure-related, and most (82, 59%) occurred in the setting of coronary artery bypass graft surgery (CABG). In a multivariable model including demographics, comorbidities and concomitant medical therapies, the only significant independent predictors of bleeding were increasing age, diabetes (DM), and CABG (model chi square 398, p < 0.001, c statistic 0.85); clopidogrel therapy beyond 28 days was not a significant predictor of major or minor bleeding. During that same interval, 80 MACE occurred. First MACE was significantly less frequent among those randomized to clopidogrel than placebo (3.0 vs. 4.7%, p=0.043).

Conclusions: With the sustained use of dual antiplatelet therapy from 1 month to one year after percutaneous coronary intervention, there is a significant 36% reduction of death, MI, and stroke without any increase in bleeding events.

1116-7

Similar Outcomes Between Patients With Native Coronary and Bypass Graft Disease Treated With Sirolimus-Eluting Stents in the SECURE Trial

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Background: Bare metal stenting or CABG has provided limited success for the treatment of bypass graft disease. The efficacy of Sirolimus-eluting Bx Velocity stents (SES) in native coronary arteries is proven, however its application in bypass grafts remains unknown. We compared the long-term results between patients with native coronary disease versus those with graft disease treated with sirolimus-eluting stents as part of SECURE trial.

Methods and Results: Patients (n=252) with a serious disease or condition for which there was no acceptable alternative treatment available were enrolled. Out of 202 patients with complete 6-month follow-up, 58 patients had 75 graft lesions (GI) and 144 patients had 286 lesions in native vessels (GII). There were more males in GI (83%) versus GII (67%). Other baseline characteristics were similar, with 39% diabetics in each group. 71% of lesions in GI and 58% of lesion in GII were treated with previous brachytherapy. All patients received aspirin and clopidogrel for at least 6 months. Angiographic vessel diameter, determined by the core lab, was larger in GI (2.26mm) versus GII (1.92mm). Likewise, in-stent MLD post procedure was 2.52mm (GI) and 2.18mm (GII). Mean total stent length was 23.3mm in both groups. There was no in-hospital adverse event in GI and 1 death (0.7%) in GII. After 6 months, 13.8% of patients in GI versus 10.4% of patients in GII had at least one major adverse event (death, myocardial infarction, target lesion revascularization or emergent CABG). TVR rate was 12.1% in GI and 9% in GII. Updated data with angiographic follow-up will be available for presentation.

Conclusion: In the SECURE trial, which enrolled a very high risk group of patients, the use of sirolimus-eluting stent to treat bypass graft disease was feasible, safe and provided acceptable long-term results compared to the outcomes of patients with native coronary disease.

Noon

1116-8

Early and Mid-Term Results of Cypher Stents in Unprotected Left Main

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The safety and efficacy of percutaneous coronary intervention in unprotected left main (ULM) coronary arteries confronts with the problems associated with restenosis.

Methods From April 2002 32 consecutive patients were electively treated in our institution with the implantation of Cypher (Cordis, Johnson and Johnson Company, Warren, NJ) Sirolimus-eluting stent (SES) in unprotected left main.

Results 4 patients (12.5%) were diabetics, 7 (22%) had unstable angina, mean age was 58±13 years, and EF was 51±6.6%. The site of the lesion in LM was ostial in 3 (9.3%) patient, mid-portion of the artery in 3 patients (9.3%) and distal in 27 (84.3%) patients (bifurcation in 21pts and trifurcation in 6). In 19 (70%) patients with distal LM disease both branches were stented with SES, kissing balloon inflation was performed in 15 (55.5%). Only POBA in side branch was performed in 3 patients (11%), 5 pts had no treatment in the side branch. The largest nominal diameter of SES available was 3.0 mm (6 cells). Angiographic as well as procedural success was achieved in all patients. Elective intra-aortic balloon pump was used in 4 patients and GP IIb/IIIa antagonists were used in 16 (50%) patients. During hospitalization, no patient died, nor had myocardial infarction (MI) or CABG, one patient had repeated PTCA due to residual dissection distal to the Cypher stent. At 6 month clinical follow-up 1 patient died after discontinuing antiaggregant therapy because of acute pancreatitis, 6 (18.7%) patients had TLR (4 re-PCI and 2 CABG) and 1 had MI. Angiographic follow-up was achieved in 23 pts (74%). Restenosis occurred in 6 patients; all restenotic lesions were located in the distal LM.

Conclusions In this early experience with Cypher stents in ULM we can state that the problem of in-stent restenosis is still present mainly at the level of the bifurcation. We can speculate that the usage of 3 mm stents (6 cells) in vessels usually larger than 3.5mm could have contributed to inhomogeneous drug delivery to the vessel wall.

Noon

1116-9

Trends in Fibrinolytic Therapy and Intra-Aortic Balloon Pump Counterpulsation Utilization in Patients With Cardiogenic Shock Complicating Acute Myocardial Infarction in Hospitals Without Percutaneous Transluminal Coronary Angioplasty/Coronary Artery Bypass Graft Capability: Observations From the National Registry of Myocardial Infarction

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Background: Treatment of patients (pts) in cardiogenic shock (CS) complicating acute myocardial infarction (AMI) with fibrinolytic therapy (FT) and intra-aortic balloon pump counterpulsation (IABP) in hospitals without PTCA/CABG capability is associated with mortality reduction.

Objectives: We determined trends in utilization of FT, IABP, and mortality rates for patients in CS complicating AMI in the National Registry of Myocardial Infarction (NRM) population for hospitals without PTCA/CABG capability.